K063652 page 1 of 3

Section 5 – 510 (k) Summary

(As required by 21 CFR 807.92(c) and 21 CFR 807.93)

FEB - 1 2007

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rebecca Lennard Regulatory Affairs Associate II Telephone: (574) 372-5023 Facsimile: (574) 371-4987 Electronic Mail: RLennard@dpyus.jnj.com
ALTERNATE 510(K) CONTACT:	Natalie Heck Manager, Regulatory Affairs Telephone: (574) 372-7469 Facsimile: (574) 371-4987 Electronic Mail: NHeck@dpyus.jnj.com
DATE PREPARED:	August 16, 2006
PROPRIETARY NAME:	DePuy Global AP™ Porous Coated Humeral Stem
COMMON NAME:	Shoulder Prosthesis
CLASSIFICATION:	Class II Device per 21 CFR 888.3670: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis Class II Device per 21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis
DEVICE PRODUCT CODE:	87 MBF 87 KWS
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Global AP™ Shoulder System, K060874 Global® Advantage Shoulder Humeral Stem with Porocoat®, K011047

DEVICE DESCRIPTION:

The subject Global AP™ humeral stems are made from titanium alloy and are porous-coated with commercially pure titanium. The stems are available in six sizes. They are identical in design to the Global AP™ Humeral Stems cleared in K060874 on June 28, 2006 with the addition of Porocoat® porous coating applied to the proximal portion of the stem.

INTENDED USE AND INDICATIONS:

Intended Use:

The subject humeral stem is designed for use as the portion of the shoulder prosthesis that replaces the proximal humerus upon which a prosthetic humeral head is attached to articulate with the natural glenoid fossa or a prosthetic glenoid replacement. The DePuy Global AP™ Porous Coated Humeral Stems are intended for cemented or cementless use, with fixation provided by biological tissue ingrowth into the porous coating.

Indications for Use:

Total Shoulder or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component).

The humeral components of the Global AP™ Shoulder are intended for cemented or cementless use as a total or hemi-shoulder replacement.

Global AP™ Porous Coated Humeral Stems are intended for cemented or cementless use, with fixation provided by biological tissue ingrowth into the porous coating.

Glenoid components of the Global AP™ Shoulder are indicated only for use with bone cement for the above indications.

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.
3. Deformity and/or limited motion.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Global AP™ Porous Coated Humeral Stem is substantially equivalent to the previously cleared DePuy Global AP™ Shoulder System (K060874) and the Global® Advantage Shoulder Humeral Stem with Porocoat® (K011047) based upon intended use, indications for use, design, materials, packaging and sterilization. The subject device does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Rebecca Lennard
Regulatory Affairs Associate II
700 Orthopaedic Drive
Warsaw, Indiana 46582

FEB - 1 2007

Re: K063652
Trade/Device Name: DePuy Global AP™ Porous Coated Humeral Stem
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBF, KWS
Dated: December 7, 2006
Received: December 8, 2006

Dear Ms. Lennard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510 (k) Number (if known): K063652

Device Name: DePuy Global AP™ Porous Coated Humeral Stem

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Global AP™ Porous Coated Humeral Stems are intended for cemented or cementless use, with fixation provided by biological tissue ingrowth into the porous coating.

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1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.
3. Deformity and/or limited motion.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(Posted November 13, 2003)

510(k) Number K063652